

Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

October 12, 2006

Brookelyn Ziegler 171 Ambroise Newport Beach, CA 92660

Dear Ms. Ziegler:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.allbaid.com and has determined that the product Allbaid is promoted for conditions that cause the product to be a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web site include:

Allbaid

- "May Lower Blood Glucose."
- "Allbaid may help to reduce blood glucose naturally."

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. Your product "Allbaid" is also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for this drug fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. While reviewing your web site, we noticed that you promoted other products for disease treatment and/or prevention. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your website, product labels, and other labeling and promotional materials

for your products to ensure that the claims you make for your products do not cause them to violate the Act.

Failure to promptly correct the violations specified above may result in enforcement action without further notice. Enforcement action may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.

Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to correct these violations, including the steps taken to assure that similar violations do not recur. Include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be addressed to Kristen Moe, Compliance Officer, Food and Drug Administration, Division of Compliance and Enforcement, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you prefer to respond electronically, send your email to kristen.moe1@FDA.HHS.GOV. If you have any questions concerning this letter, please contact Ms. Moe at 301-436-2064.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition